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APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,817	02/25/2002	Susan G. Stuart	PA-0046 US	2278
27904 7.	590 11/20/2003		EXAMINER	
INCYTE COI	RPORATION (formerly	MARTINELL, JAMES		
Genomics, Inc.) 3160 PORTER DRIVE			ART UNIT	PAPER NUMBER
PALO ALTO, CA 94304			1631	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicatio	a Na	Applicant(a)				
				Applicant(s)				
	Office Action Summary	10/084,817	7 ———————————	STUART ET AL.				
	omec Action Gammary	Examin r		Art Unit				
The MAILING DATE of this communication and		James Ma	· ·	1631				
	The MAILING DATE of this communication app ars on the cover sheet with the correspondence address Period for Reply							
THE I - Externanter - If the - If NC - Failu - Any r	ORTENED STATUTORY PERIOD FOR REI MAILING DATE OF THIS COMMUNICATION Insions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a period for reply is specified above, the maximum statutory per reto reply within the set or extended period for reply will, by state eply received by the Office later than three months after the made patent term adjustment. See 37 CFR 1.704(b).	N. 1.136(a). In no ever reply within the statut od will apply and will tute, cause the applic	nt, however, may a reply be ti tory minimum of thirty (30) da expire SIX (6) MONTHS fron cation to become ABANDONI	imely filed  sys will be considered timely.  In the mailing date of this cornmunication.  ED (35 U.S.C. § 133).				
1)	Responsive to communication(s) filed on	·						
2a)	This action is <b>FINAL</b> . 2b) ☐ Th	nis action is no	n-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims								
5) 6) 7)	4) Claim(s) is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.							
	on Papers	2, 0, 0,000,00, 10	400					
10)	The specification is objected to by the Exam The drawing(s) filed on is/are: a) a Applicant may not request that any objection to t Replacement drawing sheet(s) including the corr The oath or declaration is objected to by the Inder 35 U.S.C. §§ 119 and 120  Acknowledgment is made of a claim for fore All b) Some * c) None of: 1 Certified copies of the priority docume	nccepted or b)[ he drawing(s) be rection is require Examiner. Not eign priority und	e held in abeyance. Set of if the drawing(s) is of the the attached Office the attache	ee 37 CFR 1.85(a).  Dijected to. See 37 CFR 1.121(d).  E Action or form PTO-152.  Ea)-(d) or (f).				
13)	2. Certified copies of the priority docume 3. Copies of the certified copies of the p application from the International Bure 6 ee the attached detailed Office action for a lacknowledgment is made of a claim for dome nce a specific reference was included in the 7 CFR 1.78.  1. The translation of the foreign language acknowledgment is made of a claim for dome afterence was included in the first sentence of the content of of the conten	riority documer eau (PCT Rule ist of the certifi estic priority un- first sentence provisional app estic priority un-	nts have been received 17.2(a)).  ed copies not received as 5 U.S.C. § 119(of the specification of the specification has been recorder 35 U.S.C. §§ 120	red in this National Stage  ed. (e) (to a provisional application) or in an Application Data Sheet.  ceived. C and/or 121 since a specific				
Attachmen								
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)  4) Interview Summary (PTO-413) Paper No(s)  5) Notice of Informal Patent Application (PTO-152)  6) Other:								

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

 Claims 1-8, drawn to combinations of cDNAs and nucleic acid molecular hybridization methods, classified in class 536, subclass 23.5 and class 435, subclass 6.

- II. Claims 9-14, drawn to cDNAs, vectors, host cells, methods for producing proteins, and nucleic acid molecular hybridization assays, classified in class 536, subclass 23.5 and class 435, subclasses 320.1, 325, 252.3, and 6.
- III. Claim 15 drawn to polypeptides, classified in class 530, subclass 350.
- IV. Claims 16 and 17, drawn to screening methods for identification of compounds that bind proteins, classified in class 435, subclass 7.1.
- V. Claims 18-20, drawn to antibodies, methods of making antibodies, and antibody assays, classified in class 530, subclass 387.1 and class 435, subclass 7.1.

The inventions are distinct, each from the other for the following reasons. The nucleic acid combinations and nucleic acid molecular hybridization assays using nucleic acid combinations of Group I are materially different from, and are therefore independent and distinct from, the isolated nucleic acids and nucleic acid molecular hybridization assays using isolated nucleic acids of Group II. The nucleic acid hybridization methods of Group I may be practiced independently of the protein production methods of Group II. The nucleic acid combinations of Group I are materially different from, and are therefore independent and distinct from, the proteins of Group III and the antibodies of Group V. The methods of Group I may be practiced independently of the methods of Groups IV and V. The cDNAs, vectors, and host cells of Group III are materially different from, and are therefore independent and distinct from, the proteins of Group III and the antibodies of Group V. The cDNAs, vectors, and host cells of Group III are not needed to practice the methods of Groups IV or V. The methods of Group II may be practiced independently of the methods of Groups IV and V. The proteins of Group III have uses other than in the method of Group IV (e.g., for the production of antibodies). The proteins of Group III have uses other than in the methods of Group IV (e.g., in affinity chromatography). The proteins of Group III are

materially different from, and are therefore independent and distinct from, the antibodies of Group V.

The methods of Groups IV and V may be practiced independently of one another.

Claims 1-8 are drawn to compositions reciting different combinations of individual nucleotide sequences. Applicant is required to select one combination for examination. If the selected combination contains ten or fewer sequences, all of the sequences of the combination will be searched. If the selected combination contains more than ten sequences, the combination will be searched until one nucleotide sequence is found to be allowable. The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence. If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claims allowable. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed. See O.G. 68 (November 19, 1996).

Claims 9-14 are drawn to nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than one individual, independent, and distinct nucleotide sequence in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (November 19, 1996). This notice permits the examination of from one to ten independent and distinct nucleotide sequences in a single application based upon USPTO resources.

Should applicant elect a Group that claims or mentions more than one polynucleotide sequence, applicant is further required to select no more than ONE of the individual sequences for examination. The search of the no more than ONE selected sequence may include the complement of the selected sequence and, where appropriate, may include subsequences within the selected sequence (*e.g.*, oligomeric probes and/or primers).

Claims 15-20 are drawn to large numbers of polypeptides or mention or require the use of large numbers of polypeptides. Should applicant elect a Group that claims or mentions more than one polypeptide sequence, applicant is further required to elect one polypeptide sequence within the elected Group for examination on the merits.

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To search any two groups as outlined above would create an undue burden for the U.S. PTO because the searches of the non-patent literature are not only non-overlapping to any appreciable extent, but are also divergent in nature.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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## Reminder Regarding In re Ochiai and In re Brouwer

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner bee the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to <a href="mailed-to-james.martinell@uspto.gov">james.martinell@uspto.gov</a>. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028.

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## PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

> James Martinell, Ph.D. **Primary Examiner** Art Unit 1631